

the restrictive formulary will still always be more costly than the unrestrictive one. We then allow effectiveness and costs to vary and derive equation to calculate the cost of a restrictive formulary in those cases. We derive the equations for patients with various distributions of baseline severity. Last, we apply the equations and actual effectiveness and cost data to the case of atypical antipsychotics where Ontario and British Columbia Provincial formularies have mandated that risperidone be prescribed before quetiapine or olanzapine. **RESULT:** The cost of the restrictive status would range from \$0.87–0.97 per patient per day with mild symptoms treated with risperidone, \$2.65–3.30 for patients with moderate symptoms and \$5.14–5.73 for patients with severe symptoms. The range depends on effectiveness rates. Even if all drug costs were equal and the efficacy rates were all 80 percent, the cost per patient per day for the restrictive status of quetiapine would be \$0.66–0.71, \$1.12–1.41, \$1.67–2.26 for risperidone patient with mild moderate and severe symptoms. **CONCLUSION:** To our knowledge this is the first proof and practical application. Restrictions were removed in both provinces.

PMA5**A RISK ADJUSTMENT METHODOLOGY FOR CLAIMS DATA**

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OBJECTIVES: To develop a risk adjusted outcomes measurement system that compensates for the lack of clinical information in the claims data by dividing diseases into different stages according to the severity at various stages of the disease progression and the presence of other conditions and procedures coded in the claims database. **METHODS:** The data sources used were Medicare and a large employer's claims databases, which covered approximately 12 million and 130 thousand hospitalizations per year respectively. Rigorous data validation processes were applied to ensure data validity. Our methodology was based on the research completed by JS Gonnella, et.al., (1987) "A Clinically Based Approach to Measurement of Disease Severity", sponsored by National Center for Health Services Research, which classified diseases and combinations of diseases into different stages according to severity. Our risk adjustment system applied this approach to the principle diagnosis, secondary diagnoses and procedures coded in the claims data, to derive severity measurements for each hospitalization. In addition, we adjusted for the number of body systems involved, patient age, gender and other factors. Outcomes measurement included mortality, potentially avoidable complications, length of hospital stay, total charges and total cost. For each DRG group, logistic regression and multiple regression models were developed from the Medicare claims data to create risk adjusted norms. **RESULTS:** The model outputs were applied to the large

employer's claims data to score each patient for each outcome measurement. The results allowed for multi-dimensional comparisons on quality measurements and resource utilization measurements for all the hospitals in the large employer's database. **CONCLUSIONS:** The uniqueness of our methodology was that it adjusted for severity of diseases at various stages and combinations of diseases and number of body systems involved. It provided a more accurate means for risk adjustment than currently available.

PMA6**THE REDUCTION OF SAMPLE SIZE FOR A COST-EFFECTIVENESS TRIAL USING A NEW METHOD: THE EIGHT CASES IN JAPAN**

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At ISPOR's Third Annual European Conference, we presented a new formula that can naturally extend the traditional formula for sample-size calculation of a clinical trial, considering the cost-effectiveness ratios for two regimens A and B. **OBJECTIVE:** According to the formula, to explore applicability and validity of such a theoretical framework in real clinical trials, and then show the benefit which the new formula brings in terms of designing a prospective cost-effectiveness trial. **METHODS:** We searched and reviewed the published Japanese articles these ten years that reported socioeconomic evaluation of pharmaceuticals based on a clinical trial for two regimens: a new treatment and an old one. Subsequently we assessed the applicability and the validity of our formula in the context of such reviewed articles, and then if the formula could be applied, we calculated two sample sizes: considering effect only vs. cost-effectiveness. **RESULTS:** We reviewed eighteen Japanese articles which conducted cost-effectiveness analysis using modeling or retrospective cost evaluation after clinical trials except one prospective study. Of these eight were selected as applicable for our formula. In all of them we found that the sample size for one regimen, considering effect only vs. cost-effectiveness, can be reduced such as 1534 to 5 at the best, and 632 to 319 at the worst ratio. **CONCLUSION:** In the eight published Japanese studies, the sample size of each clinical trial considering effect only could actually be reduced if such studies are to be designed in advance as a prospective cost-effectiveness trial considering the difference of the cost-effectiveness ratios of two regimens.

PMA7**CONTROLLING FOR BIASES FROM MEASUREMENT ERRORS IN HEALTH OUTCOMES RESEARCH USING STRUCTURAL EQUATION MODELING**

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